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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/550,486	09/26/2005	Michio Kubota	KUBOTA=16	2976
1444 7590 07/28/2011 Browdy and Neimark, PLLC 1625 K Street, N.W. Suite 1100 Washington, DC 20006				
EXAMINER				
WATTS, JENNA A				
ART UNIT		PAPER NUMBER		
1781				
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07/28/2011		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/550,486

Applicant(s)

KUBOTA ET AL.

Examiner

JENNA A. WATTS

Art Unit

1781

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 May 2011.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 3 and 9 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 3 and 9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-912)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 5/26/2011 has been entered.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1, 3 and 9 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Regarding amended Claim 1, the amendment to the phrase "and other alpha-glycosyl alpha, alpha-trehalose(s)" appears to constitute new matter in light of Applicant's Paragraph 19. It is noted that Applicant's Claim 1 as previously filed was supported by Applicant's originally filed specification. Furthermore,

the deletion of the phrase "and a glucose polymerization degree of three or higher" appears to constitute new matter by deletion, in light of Applicant's Paragraph 17 where such a limitation appears to be an essential part of describing the claimed saccharide derivative of alpha, alpha-trehalose.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 1, 3, and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hasegawa (JP 09-187249) in view of Aga et al. (U.S. Patent No. 5,922,324) and further in view of Maruta et al. (U.S. Patent No. 5,610,047), all previously made of record.

8. Regarding Claims 1, 3 and 9, Hasegawa teaches a stable functional material excellent in storage stability and applicable to various kinds of food and drink without causing adverse effects on fragrance, color tone, palatability, etc. and teaches a process of homogenizing a mixture containing a functional ingredient, trehalose, an emulsifier and water and then spray-drying the emulsified functional material with a spray dryer to obtain a powdered functional material (Page 1 of machine translation of JP 09-187249, lines 15-27). Hasegawa teaches that the functional material is not restricted and can be DHA, DPA, linoleic acid, boraji oil, lecithin, rosemary, sage, beefsteak plant oil, chitosan, royal jelly, propolis, oil-soluble vitamins, etc. (Page 2, Paragraph 8). Therefore, Hasegawa teaches combining a functional material such as propolis with trehalose and powderizing the resulting mixture.

9. Hasegawa does not specifically teach that propolis is a hydrophobic non-saccharide ingredient or teach processing the hydrophobic non-saccharide ingredient into a liquid or paste by adding alcohol or organic solvent.

10. Aga teaches that propolis is a black and brown massive product and because it is mainly composed of water-insoluble hydrophobic products, it could not be readily

used and is usually used in the form of a liquid propolis extract or of a propolis tincture by dissolving it and being extracted with high concentration solutions of readily water-solvent organic solvents for example, acetone, acetic acid, and lower alcohols such as methanol, ethanol, isopropanol and in general ethanol is most favorably used (Column 1, lines 49-56). Therefore, Aga teaches that propolis is a hydrophobic ingredient and is a non-saccharide ingredient in view of Hasegawa and Claim 3, wherein the hydrophobic non-saccharide is a functional substance, and in view of the fact that Applicant discloses that propolis extract is a suitable functional substance for use with the claimed invention (see Applicant's instant specification, Page 8, line 14).

11. Therefore, it would have been obvious to one of ordinary skill in the art at the time that the invention was made, for the propolis of Hasegawa to have been processed into a liquid or paste form by adding alcohol or organic solvent, prior to combining with the trehalose and powderizing the resulting mixture, because Aga teaches that the hydrophobic property of propolis makes it not readily usable as such, and that it is usually used in the form of a liquid propolis extract that is extracted with alcohol or an organic solvent. One of ordinary skill in the art would have been motivated by Aga to first process the propolis into a liquid extract that has been extracted with alcohol or an organic solvent in order for it to be more readily used in a powdered functional composition.

12. Hasegawa in view of Aga do not specifically teach mixing the hydrophobic non-saccharide ingredient with the claimed saccharide derivative of α,α -trehalose in an amorphous form.

13. Maruka teaches methods of preparing saccharide derivatives of α , α -trehalose having a trehalose structure as an end unit and a glucose polymerization degree of 3 or higher using a novel enzyme (Column 20, lines 45-50 and 58-60) and teaches preparing a saccharide derivative comprising 8.5% PI, 68% PII, and 1.4% PIII as a non-reducing saccharide, and exhibits a DE (polymerization degree) of 3.5, and further teaches spray drying the derivative to form a powder rich in non-reducing saccharides (Column 27, Example A4, lines 20-25 and 27-30), the powder deemed an amorphous form as per Applicant's disclosure of amorphous powders (see instant specification, Page 28, lines 15 and 25-26). Maruka describes PI, PII, PIII as α -glucosyl trehalose, α -maltosyl trehalose, which is present in the claimed amount of greater than 50% w/w, and α -maltotriosyl trehalose, respectively (Column 19, lines 14-19). Therefore, Maruka is deemed to teach the claimed saccharide derivative of α , α -trehalose comprising the claimed amount of α -maltosyl trehalose and the other claimed saccharides in an amorphous form. Maruka teaches that the claimed derivative has a mild and high quality sweetness, as well as adequate viscosity and moisture-retaining ability, and these render it arbitrarily useful in food products, etc. as a sweetener, taste-improving agent, quality-improving agent, stabilizer and filler (Column 27, lines 30-35).

14. It is also noted that Applicant appears to state that the claimed saccharide derivative of α , α -trehalose can be one taught by Maruka in JP 143876/95, of which the cited US patent is the US equivalent, and Applicant discloses using any known method to prepare the claimed saccharide derivative such as by using enzymatic methods,

which are also disclosed by Maruka (see Applicant's PG Publication, Paragraphs 4 and 18).

15. Maruka teaches that the present non-reducing saccharides, including the claimed saccharide derivative of α,α -trehalose, can be used as a quality improving agent and stabilizer in biologically active substances, as well as in health foods and pharmaceuticals containing the biologically active substances, wherein such substances include propolis extract and royal jelly (Column 13, lines 40-45 and 62). Maruka teaches that by using the present non-reducing saccharides, relatively-low reducing saccharides containing them, and trehalose prepared from these saccharides, the aforementioned biologically active substances are arbitrarily prepared into health foods and pharmaceuticals with a satisfactorily high stability and quality without a fear of losing or inactivating their effective ingredients and activities (Column 13, lines 64-67 and Column 14, lines 1-5). Maruka further teaches that the methods for incorporating the present non-reducing saccharides, relatively low reducing saccharides containing them and/or trehalose prepared from these saccharides into the above mentioned compositions include conventional methods of mixing, kneading, dissolving, melting, soaking, coating, spraying, crystallizing and solidifying and further teaches adding the saccharide derivatives in an amount of about 0.1% or higher, preferably 1% or higher (Column 14, lines 5-14).

16. Therefore, it would have been obvious to one of ordinary skill in the art at the time that the invention was made, for the method of powderizing a non-saccharide ingredient such as the propolis extract of Hasegawa in view of Aga to have further

comprised substituting the claimed saccharide derivative of Maruka for the trehalose of Hasegawa in view of Aga, because Maruka teaches that the present non-reducing saccharides, including the claimed saccharide derivative of α,α -trehalose, can be used as a quality improving agent and stabilizer in biologically active substances, as well as in health foods and pharmaceuticals containing the biologically active substances, wherein such substances include propolis extract and further teaches that by using the present non-reducing saccharides and/or trehalose prepared from these saccharides, the aforementioned biologically active substances are arbitrarily prepared into health foods and pharmaceuticals with a satisfactorily high stability and quality without a fear of losing or inactivating their effective ingredients and activities. One of ordinary skill in the art would have been motivated to mix the claimed saccharide derivative of trehalose with the propolis extract of Hasegawa in view of Aga in order to provide a stable and active composition of propolis for use in health foods and pharmaceuticals.

17. Regarding Claim 1, Hasegawa in view of Aga and Maruka teach that the amount of trehalose can be suitably chosen according to the kind of functional material, and the kind of emulsifier used, but generally can be used within the limits of 0.1 to 50 parts by weight of the composition (see Hasegawa, Page 3 of the machine translation, Paragraph 9).

18. Furthermore, it would have been obvious to one of ordinary skill in the art at the time that the invention was made, to optimize the amount of saccharide derivative of trehalose used in the method of powderizing a non-saccharide ingredient, depending on the functional material used and depending on the amounts of the other ingredients

present in the composition and on the particular application of the composition. It would be within the skill of one of ordinary skill in the art at the time that the invention was made to optimize the amount of the saccharide derivative of trehalose used in the composition depending on the above mentioned factors.

19. Claims 1, 3, and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Roser et al. (U.S. Patent Application No. 2002/0012687) in view of Maruta et al. (U.S. Patent No. 5,610,047), previously made of record.

20. Regarding Claims 1, 3 and 9, Roser teaches a method of providing solid dose vehicles for delivery of bioactive materials, and to solid dose delivery vehicles comprising a stabilizing polyol and a bioactive material (Paragraph 1). Roser further teaches making the solid dose delivery vehicle by mixing the polyol, bioactive material and any other components and processing the mixture by a wide variety of methods, including milling, spray drying, air drying etc. (Paragraph 15). Roser teaches that it has now been found that stabilizing polyols, such as trehalose (Paragraph 30 and 40) can be formulated into solid vehicles suitable for drug delivery and that these stabilizing polyols have been found to be particularly useful where otherwise denaturing conditions would render impossible the formulation of solid dosage forms of bioactive materials and in particular, such conditions include the elevated temperatures and the presence of organic solvents (Paragraph 30). Roser teaches that the bioactive materials or functional substances, can include any pharmaceutical agents, including, antibiotic agents, therapeutic and prophylactic agents such as lipids, which are hydrophobic non-

saccharide ingredients and functional substances, proteins such as enzymes, biopharmaceuticals, growth hormones, as well as compositions containing prophylactic bioactive materials such as vaccines, etc. (Paragraphs 32-34).

21. Roser teaches that it has also been found that bioactive materials soluble only in organic solvents can be dried in trehalose from an organic/aqueous solvent to give a conformation that is now soluble in aqueous solvents and teaches that the bioactive agent is dissolved in organic /aqueous solvent in combination with an effective amount of trehalose and then dried (Paragraph 42). Roser teaches that trehalose has been shown to be useful in preventing denaturation of proteins, viruses and foodstuffs during dessication (Paragraph 40). Roser teaches the immunosuppressant cyclosporin A which is insoluble in water, and thus a hydrophobic non-saccharide ingredient and a functional substance, can be added in a solution of trehalose in a 1:1 ethanol/water mixture, and can be dried to give a clear glass of trehalose containing cyclosporin A (Paragraph 42). Roser teaches that this gives a solid solution of the bioactive material in a trehalose glass which then readily dissolves in an aqueous solution to give an aqueous suspension of the insoluble bioactive material. Roser further teaches milling the glass to give a free flowing powder which, if added to water, dissolves instantly (Paragraph 42). Roser teaches that the delivery vehicle is loaded with the bioactive materials to be delivered to the tissue by drying a solution of the bioactive material containing a sufficient quantity of the stabilizing polyol to form a glass on drying and this drying can be accomplished by any method known in the art, including, freeze drying, vacuum, spray, belt, air or fluidized-bed drying (Paragraph 62). Since Roser teaches

that the bioactive agent is dissolved in an organic/aqueous solvent in combination with an effective amount of trehalose, Roser is deemed to teach processing the hydrophobic non-saccharide ingredient into a liquid or paste form by adding alcohol or organic solvent and mixing the hydrophobic ingredient with trehalose. As stated above, Roser further teaches spray drying the composition, thus powderizing it.

22. However, Roser does not specifically teach mixing the hydrophobic non-saccharide ingredient with the claimed saccharide derivative of α,α -trehalose in an amorphous form.

23. Maruka teaches methods of preparing saccharide derivatives of α,α -trehalose having a trehalose structure as an end unit and a glucose polymerization degree of 3 or higher using a novel enzyme (Column 20, lines 45-50 and 58-60) and teaches preparing a saccharide derivative comprising 8.5% PI, 68% PII, and 1.4% PIII as a non-reducing saccharide, and exhibits a DE (polymerization degree) of 3.5, and further teaches spray drying the derivative to form a powder rich in non-reducing saccharides (Column 27, Example A4, lines 20-25 and 27-30), the powder deemed an amorphous form as per Applicant's disclosure of amorphous powders (see instant specification, Page 28, lines 15 and 25-26). Maruka describes PI, PII, PIII as α -glucosyl trehalose, α -maltosyl trehalose, which is present in the claimed amount of greater than 30% w/w, and α -maltotriosyl trehalose, respectively (Column 19, lines 14-19). Therefore, Maruka is deemed to teach the claimed saccharide derivative of α,α -trehalose comprising the claimed amount of α -maltosyl trehalose and further comprising the other claimed saccharides in an amorphous form. Maruka teaches that the claimed derivative has a

mild and high quality sweetness, as well as adequate viscosity and moisture-retaining ability, and these render it arbitrarily useful in food products, etc. as a sweetener, taste-improving agent, quality-improving agent, stabilizer and filler (Column 27, lines 30-35).

24. It is also noted that Applicant appears to state that the claimed saccharide derivative of α , α -trehalose can be one taught by Maruka in JP 143876/95, of which the cited US patent is the US equivalent, and Applicant discloses using any known method to prepare the claimed saccharide derivative such as by using enzymatic methods, which are also disclosed by Maruka (see Applicant's PG Publication, Paragraphs 4 and 18).

25. Maruka teaches that the present non-reducing saccharides, including the claimed saccharide derivative of α , α -trehalose, can be used as a quality improving agent and stabilizer in biologically active substances, as well as in health foods and pharmaceuticals containing the biologically active substances, wherein such substances include various pharmaceuticals including hormones such as growth hormones, antibiotics, enzymes, vaccines, vitamins such as cod liver oil, which is a hydrophobic non-saccharide ingredient (Column 13, lines 40-60). Maruka teaches that by using the present non-reducing saccharides, relatively-low reducing saccharides containing them, and trehalose prepared from these saccharides, the aforementioned biologically active substances are arbitrarily prepared into health foods and pharmaceuticals with a satisfactorily high stability and quality without a fear of losing or inactivating their effective ingredients and activities (Column 13, lines 64-67 and Column 14, lines 1-5). Maruka further teaches that the methods for incorporating the present non-reducing

saccharides, relatively low reducing saccharides containing them and/or trehalose prepared from these saccharides into the above mentioned compositions include conventional methods of mixing, kneading, dissolving, melting, soaking, coating, spraying, crystallizing and solidifying and further teaches adding the saccharide derivatives in an amount of about 0.1% or higher, preferably 1% or higher(Column 14, lines 5-14).

26. Therefore, it would have been obvious to one of ordinary skill in the art at the time that the invention was made, for the method of powderizing a non-saccharide ingredient of Roser to have further comprised substituting the claimed saccharide derivative of Maruka for the trehalose of Roser, because Maruka teaches that the present non-reducing saccharides, including the claimed saccharide derivative of α,α -trehalose, can be used as a quality improving agent and stabilizer in biologically active substances, as well as in health foods and pharmaceuticals containing the biologically active substances, wherein such substances include numerous pharmaceuticals and further teaches that by using the present non-reducing saccharides and/or trehalose prepared from these saccharides, the aforementioned biologically active substances are arbitrarily prepared into health foods and pharmaceuticals with a satisfactorily high stability and quality without a fear of losing or inactivating their effective ingredients and activities. One of ordinary skill in the art would have been motivated to mix the claimed saccharide derivative of trehalose with the hydrophobic pharmaceuticals of Roser in order to provide stable and biologically active pharmaceutical compositions that are soluble in water.

27. It would be reasonably expected that, in view of Roser and Maruta, the art recognized benefits of trehalose and the claimed saccharide derivatives of trehalose would render the trehalose and the claimed saccharide derivative suitable substitutes for each other, and therefore, it would have been obvious to one of ordinary skill in the art at the time that the invention was made, to substitute one trehalose component for another in dried pharmaceutical compositions.

28. Regarding Claim 1, Roser in view of Maruta teach that the compositions comprise an effective amount of trehalose to prepare the glass and powdered compositions (see rejection of Claim 1) and further teach embodiments comprising 20% trehalose solutions, therefore, it would have been obvious to one of ordinary skill in the art at the time that the invention was made, for the trehalose and therefore the claimed saccharide derivative of trehalose to have been used in an amount of 20% by weight in order to provide an effective amount of trehalose for the dried pharmaceutical compositions.

Response to Arguments

29. Applicant's arguments filed 5/26/2011 have been fully considered but they are not persuasive.

30. Since Applicant did not address the arguments presented in the Advisory Action mailed 5/19/2011, the Examiner refers Applicant to the arguments presented therein in addition to the arguments presented below.

31. Applicant argues that it would not have been obvious to use the claimed saccharide derivative of α,α -trehalose in a powderizing composition because the α -maltosyl α,α -trehalose is a non-crystalline saccharide and that trehalose in crystalline form has been shown to be useful as a powderizing agent in view of its crystalline structure. The Examiner respectfully disagrees with Applicant's assertion for a number of reasons.

32. Firstly, Applicant states that in Examples B-1 and B-6 of Maruta, the compositions are prepared by using the claimed saccharide derivative of α,α -trehalose, comprising the claimed amount of α -maltosyl α,α -trehalose in powder form (Applicant's arguments, Page 6). Therefore, it is submitted that if the claimed saccharide derivative can exist in powder form, it would have been reasonably expected to be able to form the powdered composition as claimed, and therefore substituting the trehalose in Hasegawa in view of Aga for the claimed saccharide derivative would have been obvious to one of ordinary skill in the art. Furthermore, Maruka teaches, as previously noted, that the methods for incorporating the present non-reducing saccharides, including the claimed saccharide derivatives, relatively low reducing saccharides containing them and/or trehalose prepared from these saccharides into the mentioned compositions, including a composition comprising propolis extract taught by Hasegawa as well, include conventional methods of mixing, kneading, dissolving, melting, soaking,

coating, spraying, crystallizing (Maruta, Column 14, lines 5-14). Since Maruta provides for using conventional methods for incorporating the claimed saccharide derivatives into compositions comprising such functional ingredients as propolis extract, it would have been obvious to one of ordinary skill in the art at the time that the invention was made, to substitute the trehalose in the method of Hasegawa, which teaches combining trehalose with propolis extract and spray drying the composition to provide a powdered composition, for the claimed saccharide derivative in view of the benefits associated with using such a claimed saccharide derivative as a stabilizer, as taught by Maruta.

33. Secondly, since Hasegawa teaches spray drying the composition to arrive at the powdered composition, it would be reasonably expected that the spray drying method itself would provide the dehydration of the resulting composition necessary to result in a powdered composition and it is unclear how the supposed non-crystalline structure of α -maltosyl α , α -trehalose would have impacted the powderizing method using spray drying.

34. Lastly, also related to the second point, in light of the fact that Applicant discloses that the specific saccharide derivatives of Maruka are suitable saccharide derivatives to be used in the claimed invention, and thus are able to be powderized via spray drying, and teaches that methods of preparing the saccharide derivatives are not restricted and that enzymatic methods can be used, which are also taught by Maruka, and Applicant does not appear to teach other special methods of preparing the powderized compositions that are necessary to alter the crystallinity of the saccharide derivatives, it is submitted that the saccharide derivatives prepared by Maruka with the claimed

amount of α -maltosyl α,α -trehalose would then be suitable to be used in a spray drying/powderizing method as taught by Hasegawa. If this is not the case, then it brings up the question of the functioning of Applicant's claimed saccharide derivative as a powderizing base.

35. Therefore, for the above mentioned reasons, the rejections as previously set forth have been maintained.

Conclusion

36. Any inquiry concerning this communication or earlier communications from the examiner should be directed to JENNA A. WATTS whose telephone number is (571)270-7368. The examiner can normally be reached on Monday-Friday 9am-5:30pm.

37. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Tarazano can be reached on (571) 272-1515. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

38. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/C. Sayala/
Primary Examiner, Art Unit 1781

/JENNA A WATTS/
Examiner, Art Unit 1781
July 22, 2011